Control of Femtosecond Thin-flap LASIK Using OCT in Human Donor Eyes

Omid Kermani, MD; Fabian Will, PhD; Ole Massow, MSc; Uwe Oberheide, PhD; Holger Lubatschowski, PhD

ABSTRACT

PURPOSE: Thin-flap keratomileusis is a procedure that minimizes LASIK flap thickness to preserve both the corneal epithelium and the maximum residual stroma. This study investigated the usefulness of optical coherence tomography (OCT) as a tool in guiding the femtosecond laser in the creation of a thin flap in human eyes in a non-randomized case series.

METHODS: In a private research laboratory, an in vitro investigation was performed on human autopsy eyes. Five human cadaver eyes, unsuitable for transplantation, underwent flap creation with a femtosecond laser. The laser procedure was controlled in real-time with an OCT system (Thorlabs HL AG) to ensure that the cut was placed just underneath Bowman's layer. The repetition rate of the femtosecond laser was 10 MHz with a single-pulse duration of <400 femtoseconds (pulse energy in the nJ range). As a control, all eyes underwent histological dissection and were examined using light microscopy.

RESULTS: Video monitoring of the flap creation supported the feasibility of real-time OCT monitoring of the femtosecond laser flap creation process. A clear distinction of the corneal epithelium was possible in all eyes. Bowman's layer was not identified in all donor eyes at the given resolution of the OCT device used in this study. Light microscopy demonstrated flaps approximately 50-μm thick, confirming that the real-time monitoring assured a positioning of the cutting plane at minimum distance underneath Bowman's layer.

CONCLUSIONS: This study of five human cadaver eyes shows that real-time OCT monitoring of the creation of thin-flaps in LASIK using a femtosecond laser is possible, thus ensuring that the flap is created at the desired depth. [*J Refract Surg.* 2010;26:57-60.]
doi:10.3928/1081597X-20101215-09

The biomechanical stability of the cornea following excimer laser ablation depends on the thickness of the residual corneal bed. Therefore, biomechanical stability is believed to be better after photorefractive keratectomy (PRK).[1] Laser in situ keratomileusis (LASIK) has the advantage of being less painful, faster in visual recovery, and associated with mild wound healing activity compared to PRK, as the corneal epithelium with its basal membrane is preserved during surgery and remains vital afterwards. However, there is substantial individual variance in the thickness of the epithelial layer.[2,3] Therefore, a system that would enable the surgeon to visualize the area of laser tissue interaction during femtosecond laser use is desirable.

In this experimental study on human donor eyes, an optical coherence tomography (OCT) system was combined with femtosecond laser to determine whether real-time OCT could be used to control LASIK flap creation.

The experimental femtosecond laser system used in this study delivers pulses in the nJ energy range to the eye and uses MHz repetition rates, leading to a cutting process that is confined by the focal spot size of the laser pulse. Because of this, the laser can be set at a closer distance to Bowman's layer.[4] The resulting gas bubbles are smaller and do not merge, which reduces the likelihood of a vertical breakthrough, even when the cutting plane is set below Bowman's layer.

MATERIALS AND METHODS

In a private research laboratory, an in vitro investigation on human autopsy eyes was performed. A larger series of porcine eyes and five human donor eyes, unsuitable for transplantation, underwent LASIK flap creation with a femtosecond laser. All human eyes had some stromal and epithelial

From Augenklinik am Neumarkt, Cologne (Kermani, Oberheide); Rowiak GmbH, Hannover (Will); and Laser Zentrum Hannover e.V., Hannover (Massow, Lubatschowski), Germany.

The authors have no proprietary interest in the materials presented herein.

This paper was presented at the Lens, Refractive & Wavefront Summit ARI/WFC 2009; March 5-7, 2009; Alicante, Spain.

Correspondence: Omid Kermani, MD, Augenklinik am Neumarkt, Schildergasse 107-109, 50667 Cologne , Germany. Tel: 49 221 65072271; Fax: 49 221 65072279; E-mail: o.kermani@augenportal.de

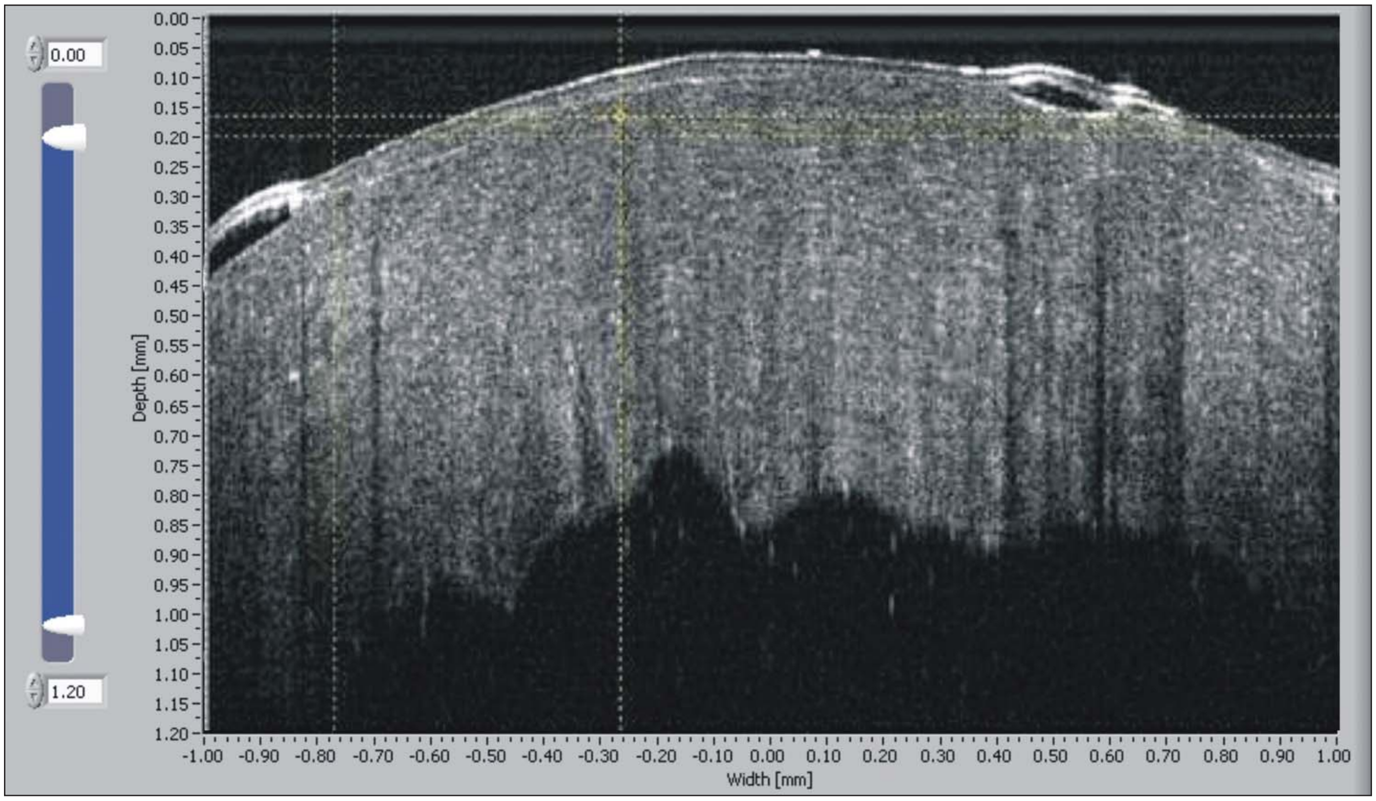

Figure 1. Control interface for monitoring the surgical procedure with an optical coherence tomography image of the cornea. The dark areas on the top left and right indicate separation of the flap beneath Bowman's layer by a residual gas bubble.

edema present, but the details of the anterior chamber structures were visible.

The eyes were fixated by placing them cornea downward on an applanation window of the experimental set-up and then secured by a ring-like holder. Applanation was achieved by applying slight downward pressure on the posterior of the globe. Once the eye was fixed on the applanation mask, it was ensured that the OCT (Thorlabs HL AG, Lübeck, Germany) and video camera delivered an adequate image of the cornea. The OCT system operates at a wavelength of 930 nm and has a spatial resolution of 6.2 µm axial and 9.2 µm lateral. The acquisition time of the OCT system was 10 frames per second.

The femtosecond laser used (T-Pulse 200; Amplitude Systemes, Pessac, France) had a wavelength of 1030 nm, a repetition rate of 10 MHz with a single-pulse duration of 250 to 400 femtoseconds, an average power of 200 to 400 mW, and a single-pulse energy of 10 to 50 nJ.

All beam paths, the femtosecond laser, the OCT signal, and the video signal were aligned collinear by dichromatic mirrors. In OCT mode, the interface of the computer control enables the surgeon to preset the laser-cutting plane at any desired position within the anterior stroma. For the purpose of this study, the femtosecond laser cut was set underneath the interface of epithelium and stroma at a distance of 15 µm. Flaps were created using a raster pattern. The entire applanated cornea was not visualized with OCT—only the area around the laser tissue interaction zone was under visual real-time control with the OCT device. It was necessary to adjust the depth of the flap only once at the beginning of the cutting process. No other adjustments were necessary at the chosen depth of the laser setting.

After flap creation, the cutting plane could be identified based on the bubble layer. This induced bubble layer was less pronounced compared to bubble layers seen with commercially available femtosecond lasers and dissipated within 1 to 3 minutes. Flap lift was done with a pinpoint, blunt spatula and then repositioned. The histological samples were taken near the greatest diameter of the flap, perpendicular to the cutting plane. Although the femtosecond laser pulses were applied at a high repetition rate (10 MHz), there were no signs of thermal or mechanical damage in the tissue layers adjacent to the cutting plane.

RESULTS

Once the corneal layers were identified on the system's OCT image, the cutting plane could be adjusted.

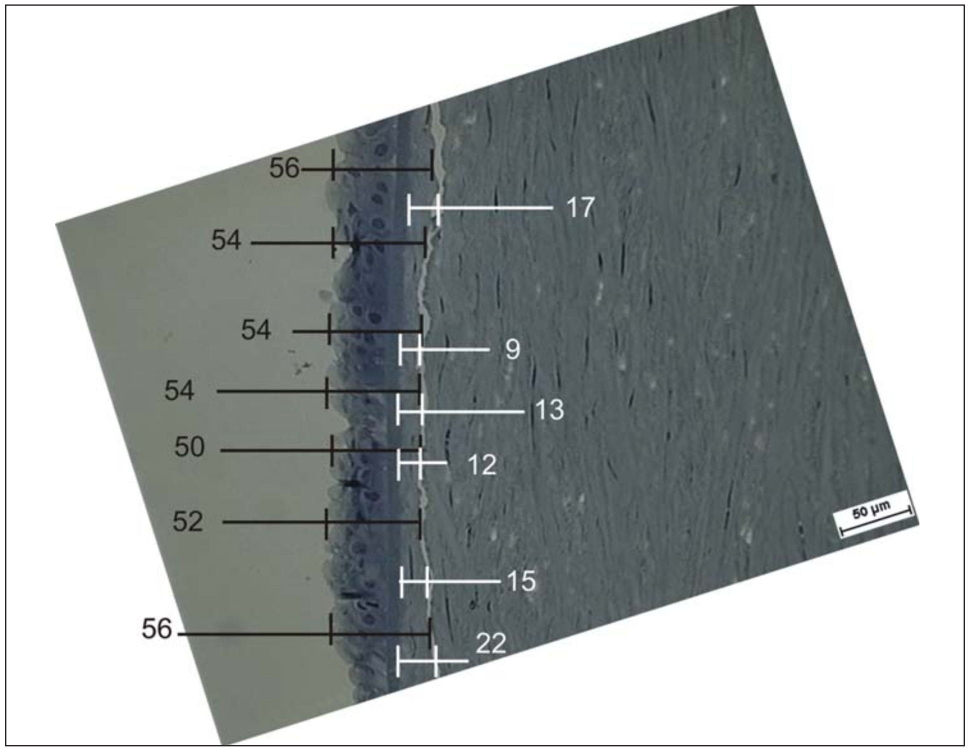

Figure 2. Histological processing with toluidine blue of a human donor eye after thin-flap keratomileusis using an optical coherence tomography–guided femtosecond laser. Black numbers show total flap thickness; white numbers show the distance from the cut to Bowman's layer in microns.

The cutting process could be monitored in real-time on the OCT image. This ensured that the preset flap thickness was maintained and that no perforation had occurred during the flap cut. The merging gas bubbles, induced by the femtosecond laser interaction, were noted in all procedures. In no eyes did the gas bubbles break through the anterior corneal lamellae and Bowman's layer. The gas underneath the flap led to a clear distinction of the stage of the surgical procedure and was also monitored in real-time during the surgical procedure (Fig 1).

The video monitoring of the laser process supported the feasibility of the concept of real-time monitoring via OCT. A clear distinction of the corneal epithelium was possible in all eyes. In some eyes, Bowman's layer could not be clearly visualized due to the previously mentioned edema. However, the transition between epithelium and stroma (Bowman's layer) could be identified, which provides sufficient evidence for the cutting plane.

Dissection and lifting of the flap were possible in all eyes. All flaps were intact; no perforation occurred in any procedure. Light microscopy of the histological samples (taken from a mid-periphery section of the flap) confirmed the position of the cutting plane at minimum distance beneath Bowman's layer in the five cadaver eyes. Flap thickness was controlled on the histological processings and confirmed the operative settings of 50±5 µm (Fig 2).

DISCUSSION

Commercially available femtosecond lasers, such as the IntraLase FS Femtosecond Laser (Abbott Medical Optics [AMO], Santa Ana, Calif), have demonstrated that it is possible to cut corneal flaps with a higher degree of precision compared to mechanical microkeratomes.[5,6] With a standard deviation in the range of approximately ±5 to 10 µm, the IntraLase laser enables the surgeon to safely and predictably cut flaps as thin as 90 to 100 µm.[7] This thickness takes an estimation of the epithelial layer and Bowman's layer into account but does not provide a patient-specific measurement.

The corneal epithelium is not uniform in thickness.[2,3] Only a central measurement would not be appropriate on which to base the ablation depth. Therefore, visual diagnostic control of the layers of the treated cornea should encompass the entire treatment zone.

We present results of a principle study of OCT-guided, femtosecond laser LASIK flap creation in human cadaver eyes with closer distance to Bowman's layer. Prior to the experiments on human eyes, 2 years of work was necessary to develop the experimental set-up and extensive work was done on fresh porcine eyes.[8] In this trial, we could measure the thickness of the epithelial layer but determining the thickness of Bowman's layer was difficult due to the axial resolution of 6 µm compared to the typical thickness of 10 to 20 µm for Bowman's layer. Although one could add the typical thickness of Bowman's layer to the epithelial layer when defining the cutting depth, a higher axial resolution of the OCT would be helpful to determine Bowman's layer more accurately. The spatial resolution of OCT measurements depends on the width of the spectrum of the light source, the numerical aperture of the focusing optics, and the measurement time. Recent laboratory-based OCT systems have a resolution of better than 3 µm and a data acquisition time of better than 100 Hz per frame.[9] This shows that, in principle, there is no technical limitation to have sufficient control of the laser cut with OCT technology.

AUTHOR CONTRIBUTIONS

Study concept and design (O.K.); data collection (F.W., O.M., H.L.); interpretation and analysis of data (O.K., F.W., U.O., H.L.); drafting of the manuscript (O.K.); critical revision of the manuscript (O.K., F.W., O.M., U.O., H.L.); administrative, technical, or material support (F.W., O.M., U.O.)

REFERENCES

1. Schmack I, Dawson DG, McCarey BE, Waring GO III, Grossniklaus HE, Edelhauser HF. Cohesive tensile strength of human LASIK wounds with histologic, ultrastructural, and clinical correlations. *J Refract Surg.* 2005;21:433-445.
2. Reinstein DZ, Archer TJ, Gobbe M. Stability of LASIK in topographically suspect keratoconus confirmed non-keratoconic by Artemis VHF digital ultrasound epithelial thickness mapping: 1-year follow-up. *J Refract Surg.* 2009;25:569-577.
3. Reinstein DZ, Archer TJ, Gobbe M. Corneal epithelial thickness profile in the diagnosis of keratoconus. *J Refract Surg.* 2009; 25:604-610.
4. Ripken T. *Anwendung von MHz-fs-Lasern in der Ophthalmologie und Erarbeitung eines Therapiekonzeptes für die laserassistierte Behandlung der Alterssichtigkeit.* [PhD thesis]. Hannover, Germany: University of Hannover; 2007.
5. Binder PS. Flap dimensions created with the IntraLase FS laser. *J Cataract Refract Surg.* 2004;30:26-32.
6. Sarayba MA, Ignacio TS, Tran DB, Binder PS. A 60 kHz IntraLase femtosecond laser creates a smoother LASIK stromal bed surface compared to a Zyoptix XP mechanical microkeratome in human donor eyes. *J Refract Surg.* 2007;23:331-337.
7. Stahl JE, Durrie DS, Schwendeman FJ, Boghossian AJ. Anterior segment OCT analysis of thin IntraLase femtosecond flaps. *J Refract Surg.* 2007;23:555-558.
8. Massow O, Jackstadt M, Wisweh H, Will F, Lubatschowski H. OCT-aided femtosecond laser micromachining device. *Proceedings - Society of Photo-Optical Instrumentation Engineers (SPIE).* 2009;7203:72037. doi:10.1117/12.808754.
9. Potsaid B, Gorczynska I, Srinivasan VJ, Chen Y, Jiang J, Cable A, Fujimoto JG. Ultrahigh speed spectral/Fourier domain OCT ophthalmic imaging at 70,000 to 312,500 axial scans per second. *Opt Express.* 2008;16:15149-15169.